

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

STATUS OF CLAIMS

Claims 4, 6-9, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38-39 are pending in the application. Of the above claims, claims 4, 6, 8, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 stand rejected, claims 7 and 9 are withdrawn. Applicants note that the PTO did not indicate the status of pending claim 39, which is believed elected/rejected.

REJECTION UNDER 35 U.S.C. § 103(a)

The PTO rejected claims 4, 6, 8, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 as obvious over SmithKline Beecham Co. (WO 95/06410) in view of Katz et. al. (US Pat. 5,028,435). Applicants respectfully traverse.

In particular, Applicants point out that neither of the cited references teaches a skin permeability regulator comprising 1) a fatty acid ester, 2) a polyol and 3) a nonionic surfactant. Applicants note that, although Katz presents a long list of permeability enhancers which includes among others fatty acid esters, non ionic surfactants and propylene glycol (see Katz, column 5, line 56, through column 6, line 2), Katz does not expressly teach a skin permeability regulator comprising a combination of three components: a fatty acid ester, a polyol and a nonionic surfactant of the claimed invention.

Moreover, one of ordinary skill in the art would not have the required motivation or the required reasonable expectation of success to select the combination of fatty acid ester, a polyol and a nonionic surfactant from the Katz's extensive list the claimed combination of permeability enhancers for a compound having angiotensin II antagonistic activity. Katz expressly states that "the selection of drug, matrix layer, and chemical penetration enhancer cannot be made independently. Rather, the nature of the drug and the enhancer are interdependent as the enhancer must be selected to provide for transport of that drug across the skin or membrane of the host" (Katz, column 6, lines 3-9). However, Katz does not

provide any specific criteria for selecting a particular permeability enhancer for a particular drug, nor does Katz teach any particular permeability enhancer or combination of enhancers compatible with a compound having angiotensin II antagonistic activity. Accordingly, one of ordinary skill in the art could only arrive at a combination of (1)-(3) by chance, i.e., quite the opposite of the required motivation and expectation of success.

Along these lines, Applicants respectfully note that the experimental examples of the instant application demonstrate that claimed skin permeability regulator comprising 1) a fatty acid ester, 2) a polyol and 3) a nonionic surfactant is extremely compatible with compounds having angiotensin II antagonistic activity in compositions for transdermal administration (see Examples 1, 2 and Test Example).

In conclusion, since neither the '410 publication, nor Katz teach a skin permeability regulator comprising a fatty acid ester, a polyol and a nonionic surfactant, Applicants respectfully request withdrawal of the rejection.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to

Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 8/4/2005

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5571
Facsimile: (202) 672-5399

By *Alexey Saprin* (^{Reg. 156,439})
Alexey Saprin
FOR Harold C. Wegner
Attorney for Applicant
Registration No. 25,258